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Abbott withdraws application to market briakinumab for psoriasis

JANUARY 15TH 2011 BY PSORIASIS CURE NOW

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Abbott today announced in a securities filing that it has withdrawn its application with the U.S. Food and Drug Administration (FDA) and European regulators to market its much-anticipated, experimental psoriasis treatment briakinumab (ABT-874, Ozespa). The biologic, like Centocor Ortho Biotech's Stelara (ustekinumab), targets two internal proteins linked to inflammation, IL-12 and IL-23. Briakinumab has demonstrated very powerful effectiveness in improving psoriasis symptoms, and has been the subject of much fawning coverage. Psoriasis Cure Now threw a rare splash of cold water on the proceedings in our analysis of briakinumab's four pivotal psoriasis clinical trials. While we lauded its effectiveness, we reminded readers that "effectiveness is only one side of the equation. Patients also need treatments that are safe." The trials raised safety concerns that we seemed puzzled were not generating attention in the health care media or among other nonprofits. Today's announcement that Abbott has withdrawn its application, unfortunately confirms our suspicions.

In its filing, Abbott wrote: "Following feedback from regulatory authorities indicating the need for further analysis and the potential for additional studies, the company plans to evaluate next steps for briakinumab, including resubmission at a later date." This suggests the FDA and its European counterpart want to see more evidence on the safety side of the equation for briakinumab (Ozespa). Fortunately, several studies of briakinumab are ongoing.

"We certainly hope Abbott will continue these studies and that they will demonstrate that briakinumab's benefits outweigh its risks," said Michael Paranzino, president of Psoriasis Cure Now and a psoriasis patient. "Psoriasis patients need additional treatment options, particularly those for whom the anti-TNF therapies have not worked or are not appropriate. Given briakinumab's eye-catching effectiveness in clinical trials, we certainly hope this treatment option can soon become available for patients who need it. No treatment is without risk, but we can't quarrel with the FDA, given what we know today, for wanting to see some more data. The FDA, however, must be mindful that moderate to severe psoriasis can have a devastating impact on quality of life, and other treatments also carry risks."

Abbott's CFO this week referred to briakinumab as a "decent product," an unusually lukewarm description of a product that has been much buzzed about at dermatology meetings and on psoriasis message boards. Let's hope that was designed to calm investors concerns about this announcement, and not a signal that Abbott is losing interest in this potential treatment, or that they are seeing additional data not yet released publicly that causes greater concern. A Wells Fargo analyst today predicted a "multiyear delay" for briakinumab.

For psoriasis patients, it's a painful reminder how very hard and expensive and time-consuming it is for pharmaceutical and biotech companies to find new and better treatments that are both safe and effective. It will also put additional spotlight on Stelara's safety record, as its mechanism of action is similar. So far, Stelara has not seen this level of concern and of course, it has already been approved by US and European regulatory bodies.

Still, the psoriasis treatment research pipeline remains robust, and there are numerous treatment options that are helping psoriasis patients right now. We won't spin you, this is disappointing news, but there is great reason to be optimistic nonetheless.

Category: Biologics, Psoriasis Research, Side-effects of treatment

Tags: Abbott, ABT-874, Briakinumab, FDA, Stelara, ustekinumab

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Lori Pritchard

FEBRUARY 2, 2011 AT 9:46 AM

I participated in phase I of the trial and had very good results with no side effects.

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John H. Szalkay
FEBRUARY 11, 2011 AT 2:49 AM

I am on week #109 of the 156 week clinical trial. For the first time in about 57 (yes, fifty-seven) years of severe plaque psoriasis, I am 100% free of it. No side effects whatsoever! So, another good medication bites the FDA's dust – what percentage of people on the clinical trial have or had serious side effects? Even aspirin has some – luckily, there were no approvals needed when it was introduced well over 100 years ago.

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